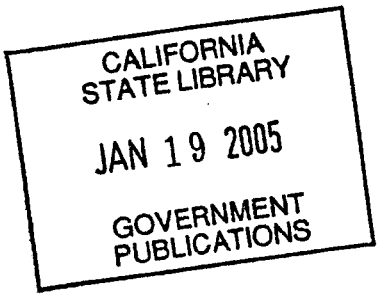
c.2

REPORT TO THE LEGISLATURE



DRUG MANUFACTURING, MEDICAL DEVICE MANUFACTURING, AND HOME MEDICAL DEVICE RETAILER LICENSING COSTS AND FEE ANALYSIS

ANNUAL REPORT

DIVISION OF FOOD, DRUG, AND RADIATION SAFETY
CALIFORNIA DEPARTMENT OF HEALTH SERVICES

2003

EXECUTIVE SUMMARY
REPORT TO THE LEGISLATURE

DRUG MANUFACTURING, MEDICAL DEVICE MANUFACTURING, AND HOME MEDICAL DEVICE RETAILER LICENSING COSTS AND FEE ANALYSIS ANNUAL REPORT

The Department of Health Services (DHS), Food and Drug Branch (FDB) is responsible for licensing all manufacturers of pharmaceutical drug products (e.g., blood pressure medications) and medical devices (e.g., heart pacemakers) in California. FDB inspects drug and medical device facilities every two years to assure they are operating in compliance with the California Health and Safety (H&S) Code and federal Good Manufacturing Practices (GMP) regulations to assure the products are safe and effective. DHS currently licenses and inspects 1,275 drug and medical device manufacturers in California. These firms currently pay an annual license fee per facility of $402.31. DHS must inspect 485 of these facilities annually to meet mandated requirements. Assembly Bill (AB) 1496 (Olberg, Chapter 837, Statutes of 2000) and Senate Bill (SB) 724 (Figueroa, Chapter 728, Statutes of 2001) require annual fees be adjusted to support the estimated costs of the drug and medical device licensing and inspection program. This fee adjustment is proposed to take place over a two-year period in order to minimize the impact to industry. DHS proposes to increase fees from the current annual $402.31 to a fee ranging from $625 to $1,000 in fiscal year (FY) 2003-04 and $850 to $1,600 in FY 2004-05. The specific fee for each license will be based on the complexity of the inspection. The fee adjustment is needed to support 12 investigative staff. Each investigator can inspect 40 drug and medical device firms per year.

DHS is also responsible for licensing and inspecting all Home Medical Device Retailers (HMDR) in California that sell and rent medical devices and medical oxygen to the public. AB 1496 (Olberg, Chapter 837, Statutes of 2000) initiated the DHS licensing program for HMDR facilities. There are currently 2,080 HMDR facilities and the annual license fee per facility is $850. The existing fees for HMDR licenses set by the Legislature are sufficient to support the HMDR licensing and inspection program for the next fiscal year. The HMDR program requires a minimum of 11 full time investigative and administrative staff to complete required inspections and perform licensing activities for HMDR facilities and warehouses, evaluate qualifications of 1,200 HMDR Exemptees employed to supervise facilities, and investigate fraud and other violations. Each investigator can inspect 300 HMDR firms per year.

H&S Code Section 111656.1 (e) requires DHS to annually publish a Report to the Legislature each January 10 recommending the amount of license fees to be charged to drug, medical device, and HMDR facilities for the next fiscal year beginning on July 1. Annual license fees are to be based on estimated program costs, taking into account the costs for inspections and other required activities. The fees collected will be deposited into the Drug and Device Safety Fund (DDS Fund) to carry out and implement the licensing provisions of H&S Code Division 104, Part 5, Chapter 5, Article 6.

TABLE OF CONTENTS

I. INTRODUCTION 1

A. Statutory Requirement for Report to the Legislature 1
B. Background 2
C. Structure of Programs 3

II. LICENSE INSPECTION ACTIVITIES 3

A. Drug Manufacturing License Inspections 3
B. Medical Device Manufacturing License Inspections 5
C. Home Medical Device Retailer License Inspections 6

III. ACTIVITIES, LICENSE FEES, AND COST ANALYSIS 7

A. License and Inspection Activities 7
B. Fee Categories and Inspection Workload 8
C. Current Estimated Revenue and Estimated New License Fees 11

IV. Attachments 13

I. INTRODUCTION

A. Statutory Requirement for Report to the Legislature

The California Department of Health Services (DHS) is pleased to submit this initial annual report recommending proposed Drug Manufacturer, Medical Device Manufacturer, and Home Medical Device Retailer (HMDR) License Fees for fiscal year (FY) 2003-04, as required by the Home Medical Device Retailer Facilities Act of 2000 (The Act). DHS has been required to inspect and license drug and medical device manufacturers since 1970, pursuant to California Health and Safety (H&S) Code Section 111635. The H&S code also adopted existing and future federal good manufacturing practices (GMP) regulations for drugs and medical devices (H&S Code Section 110105) that establish basic quality assurance standards for manufacturers. In 2000, Assembly Bill (AB) 1496 (Olberg, Chapter 837, Statutes of 2000) required the licensing of HMDR facilities by DHS. The Act sets specific facility and operational performance standards and requires DHS to perform inspections prior to licensing each facility and annually thereafter. The Act also requires DHS to provide the Legislature with an annual report recommending proposed license fee changes based upon the estimated licensing and inspection costs to fully support the program. H&S Code Section 111656.1 (e) states:

> *Commencing January 1, 2003, the department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.*

H&S Code Section 111656.1 (d) requires DHS to publish, by July 30 of each year, the amount of license fees to be charged for the new fiscal year. This adjustment of fees is not subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Moneys collected under this section are deposited into the Drug and Device Safety Fund (DDS Fund) to carry out and implement the provisions of HSC Division 104, Part 5, Chapter 5, Article 6. Article 6 covers licensing provisions and does not include the costs of other drug and medical device activities and investigations mandated in H&S Code Division 104, Part 5, Chapter 5.

This report describes the activities supported by the DDS Fund and the estimated costs of the licensing and inspection programs for FY 2003-04. These estimated costs support the recommended increases for Drug and Medical Device Manufacturing License fees for FY 2003-04. HMDR facility license fees are sufficient to fully support

the program and should remain the same. The proposed new fees will only adequately support licensing activities.

B. Background

In California, the safety, effectiveness, manufacture, and labeling of drugs and medical devices has been regulated since 1907 when the Pure Drugs Law was enacted. In 1963, DHS licenses were required for manufacturers of drugs, and, in 1970, DHS began licensing medical device manufacturers. Standards for medical devices were not separated from drug standards until 1978 when the federal government promulgated regulations differentiating drugs from medical devices. DHS did not begin licensing HMDR facilities until January 2002, replacing licensing programs by the Board of Pharmacy and the Bureau of Household Furnishing and Thermal Insulation.

License fees for drug and medical device manufacturers have been required since 1970. These fees began as "registration fees" and have slowly increased, but have never been adequate to pay for the actual costs of license inspections that often take weeks to complete. The current fee for a Drug or Medical Device Manufacturing License is $402.31. This fee does not take into account the complexity of the inspection, whether the inspection is a new or a renewal inspection, and the actual time needed to complete the licensing process. The fees for HMDR Licenses were based upon the concept that the services provided be fully fee supported. HMDR fees pay not only for the cost of the licensing inspection, but also the cost of applying and issuing a new or renewal license.

The inspection of new license applicants is of the highest priority. Businesses are required to be licensed prior to initiating manufacturing or distribution of the specified commodities. The number of new license applications is steadily increasing. New license inspections, except HMDR facilities, generally take longer to complete than re-inspections. This is because there is much more data collected on new firms, more compliance problems are detected, and more onsite-training is provided. Licensed renewing firms are generally in greater compliance; DHS program information is more complete and builds on past inspections.

The U.S. Food and Drug Administration (FDA) also plays a role in regulating drugs and medical devices in California. FDA and DHS have partnered to provide more oversight of these industries. FDA has taken the lead in regulating imported drug and medical devices at the point of entry. FDA has primary responsibility for approving new drugs and medical devices. FDA also inspects a number of manufacturers each year (less than 20 percent of those in California). Through partnership agreements, these inspections are not duplicated by DHS and the results of FDA and DHS inspections are shared. Despite this cooperation, the frequency of inspections of each drug and medical device manufacturer is less than once every two years as required by law. In addition, FDA generally does not inspect new manufacturers until two to three years after they have initiated manufacturing. The new license inspection provided by DHS benefits both new manufacturers and consumers by ensuring that new manufacturers comply with design and testing standards and all applicable laws and regulations. Because these products are used to treat life-threatening diseases or are necessary for life-support, early regulation by DHS prevents product contamination and misbranding

and a variety of formulation, fabrication, and labeling problems. FDA does not inspect or regulate HMDR facilities or optical lens laboratories that are inspected and licensed by DHS. Since FDA has a role in regulating the drug and medical device industry, their estimate of inspection activities is used to reduce the projected costs of DHS' Drug and Medical Device Licensing Programs. FDA's drug and medical device manufacturer inspection workload will be reassessed in the annual legislative report regarding proposed drug and medical device license fees for FY 2004-05.

C. Structure of Programs

Drug and medical device safety are regulated by DHS' Prevention Services' Division of Food, Drug, and Radiation Safety (DFDRS). Within DFDRS, the Food and Drug Branch (FDB) inspects and licenses drug and medical device manufacturers and HMDR facilities. Inspections of drug and medical device manufacturers and HMDR facilities are performed by FDB's Food and Drug Investigators.

The licensing inspection requirements for drugs and medical device manufacturers and HMDR facilities are different. While inspection time for HMDR facilities is generally uniform, licensing inspections for drug and medical device manufacturers fall into three general types: new license applicants, renewal of licenses, and licensing of small or simple manufacturers. The licensing cost analysis and estimation of the appropriate licensing fee is displayed separately for each type of inspection (see section III.B. pages 9 and 10). HMDR facility licensing is a separate and unique program from the drug and medical device licensing programs and all of the program and licensing requirements appear in Article 6 of H&S Code Division 104, Part 5, Chapter 5. All of the HMDR program costs, including supervision and support functions, are intended to be supported by HMDR license fees.

II. LICENSE INSPECTION ACTIVITIES

A. Drug Manufacturing License Inspections

H&S Code Section 109875 *et seq.* has required DHS to license all manufacturers of drug products since 1963. The purpose of these inspections is to prevent the sale and distribution of drugs that:

1. have been improperly manufactured;
2. are adulterated, misbranded, or falsely advertised; or
3. have not been shown to be safe and effective.

DHS is required to inspect the place of manufacture prior to issuing a new drug manufacturing license; firms cannot legally manufacture without a valid license. DHS is required to inspect each licensed manufacturer once every two years (renewal inspections); additional inspections may be conducted "for cause" (e.g., to investigate injuries and deaths, to investigate product recalls). A license may be denied, suspended, or revoked by DHS if the manufacturer is found in violation of any applicable part of the Sherman Food, Drug, and Cosmetic Law (H&S Code Section 109875 *et seq.*).

The drug manufacturing inspection and licensing program is intended to prevent drug failures due to a manufacturing error.

DHS licensing inspections are effective because they provide:

- assurance that new manufacturers have effective systems in place before they begin manufacturing and shipping drugs;
- assurance that drug processes are properly validated;
- assurance that firms have qualified personnel performing critical process steps;
- assurance that critical process steps, such as sterilization, are validated to be effective and that firms consistently follow validated procedures;
- assurance that firms promptly investigate drug failures to minimize patient exposure and identify their root cause, and that corrective and preventive actions are taken so that additional failures do not occur;
- assurance that firms investigate all problems that are identified during manufacturing or reported by customers, and that corrective and preventive actions are taken to prevent future problems;
- education as needed to help industry understand and comply with manufacturing requirements; and
- information indicating when enforcement action is needed to prevent the distribution of unsafe or ineffective drugs.

Product failures do occur and there are hundreds of drug product recall announcements issued annually. Many of these involve products manufactured in California by DHS licensed manufacturers. Other products are imported into California. Examples of recent drug processing and handling errors include:

- patient infections from pre-filled syringes and surgical scrubs contaminated during manufacturing;
- adverse reactions because the wrong drug was placed in the package;
- medical oxygen cylinders shipped empty to customers;
- manufacturing with no testing of prescription drugs;
- repackagers mixing up the strength of finished tablets;

Periodic inspections of manufacturers allow for identifying and correcting conditions that produce defective products that put our population at risk. Many of these problematic conditions are unique to California and require State regulatory action to best protect the consumer from dangerous products. Ensuring that drug manufacturers meet current GMP requirements and comply with all applicable H&S Code requirements as a prerequisite for licensing prevents unqualified and unprepared firms from placing drugs in the hands of medical practitioners and the consumer.

In 1988, the federal Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 100-293, 102 Stat. 95), was enacted in response to serious public health and safety problems associated with the "diversion market" for prescription drugs. Congress found that adulterated, mislabeled, sub-potent, expired, or counterfeit drugs were easily introduced into the national distribution system due to the operation of a wholesale sub-market, commonly know as the "diversion market," where drug products are obtained from

sources outside of normal channels of distribution. In 1990, FDA published final regulations establishing state guidelines for the minimum requirements for prescription drug storage and security, as well as for the treatment of returned, damaged, and outdated prescription drugs. Further, wholesale drug distributors were required to establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs and make these available for inspection and copying by authorized federal, state, or local law enforcement officials. In 1992, California adopted emergency regulations conforming to these FDA requirements, and now DHS must inspect prescription drug manufacturers for compliance with PDMA regulations.

B. Medical Device Manufacturing License Inspections

H&S Code Section 109875 *et seq.* has required DHS to license all manufacturers of medical devices since 1970. The purpose of this program has been to prevent the sale and distribution of medical devices that:

1. have been improperly manufactured;
2. are adulterated, misbranded, or falsely advertised;
3. have not met design validation requirements; or
4. have not been shown to be safe and effective.

DHS is required to inspect each place of manufacture prior to issuing a new Medical Device Manufacturing License. Firms cannot legally manufacture without a valid license. DHS is required to inspect each licensed manufacturer once every two years (renewal inspections). Additional inspections may be conducted "for cause" (e.g., to investigate injuries and deaths, to investigate product recalls). A license may be denied, suspended, or revoked by DHS if the manufacturer is found in violation of any applicable part of the Sherman Food, Drug, and Cosmetic Law (H&S Code Section 109875 *et seq.*).

The medical device manufacturer inspection and licensing program is intended to prevent medical device failures due to manufacturing error. DHS licensing inspections are effective because they provide:

- assurance that new manufacturers have effective systems in place before they begin manufacturing and shipping medical devices;
- assurance that medical devices are designed and processed with proper validation;
- assurance that firms have qualified personnel performing critical process steps;
- assurance that critical process steps such as sterilization are validated to be effective, and that firms consistently follow validated procedures;
- assurance that firms promptly investigate medical device failures to minimize patient/consumer exposure and identify their root cause, and that corrective and preventive actions are taken so that additional failures do not occur;
- assurance that firms investigate all problems that are identified during manufacturing or reported by customers, and that corrective and preventive actions are taken to prevent future problems;

- education as needed to help industry understand and comply with manufacturing requirements; and
- information indicating when enforcement action is needed to prevent the distribution of unsafe, ineffective, or mislabeled medical devices.

Product failures do occur and there are hundreds of medical device recalls completed annually. Many of them involve products manufactured in California by DHS licensed manufacturers. Others are products imported into California. Examples of recent instances include:

- inadequate sterilization of implantable heart valves causing patients to become ill and sometimes die from infections;
- devices such as defibrillators and ventilators that fail to function as designed, placing patients in life-threatening situations;
- laboratory diagnostic kits that give false positives (or negatives) resulting in misdiagnosis and possible improper medical treatment (or non treatment);
- knee and hip joints that fail prematurely resulting in additional surgery and replacement to the patient;
- the manufacture of devices such as magnetic mattress pads and metal bracelets that are advertised and sold to cure cancer and other serious diseases with no scientific data to support these claims;
- the recall of latex surgical gloves containing holes; and
- the investigation of prescription (dangerous) medical devices that are sold directly to consumers without adequate direction or medical supervision.

Periodic inspections of manufacturers allow for identifying and correcting conditions that produce defective products that put the population at risk. Many of these problematic conditions are unique to California and require State regulatory action to best protect the consumer from dangerous products. Ensuring that medical device manufacturers meet current GMP requirements, meet requirements set for the three Classes of medical devices, and comply with all applicable H&S Code requirements as a prerequisite for licensing, prevents unqualified and unprepared firms from placing medical devices in the hands of medical practitioners and the consumer.

C. Home Medical Device Retailer License Inspections

The licensing of HMDR facilities is important to protect California consumers from unsafe, contaminated medical devices and adulterated prescription medical oxygen. The licensing program also provides protection to consumers, insurance companies, and Medi-Cal from fraudulent activities at unlicensed HMDR facilities. Mandated license inspections ensure that competent and knowledgeable persons dispense, repair, calibrate, and maintain prescription devices and sell prescription medical oxygen. The wide variety of medical devices and how they are assembled, maintained, cleaned, sanitized, and utilized require regulatory oversight. DHS' oversight ensures that HMDR facilities distributing or selling medical devices such as ventilators and oxygen concentrators, or providing drug delivery systems for home medication, hospital beds, traction equipment, and other medical devices, are competent and safely allow consumers to be treated or convalesce at home. Prescription medical oxygen is also

inspected by DHS to ensure that it is suitable for life support. FDB coordinates its inspection findings with the Medi-Cal Provider Enrollment Branch (PEB), the Medi-Cal Fraud Prevention Bureau, and the Audits and Investigations Branch to eliminate fraud by identifying HMDR facilities that are empty storefronts designed to falsely bill for products never sold or utilized.

In cooperation with PEB, FDB inspections verify certain business information and business activities supplied by Medi-Cal providers on various documents. These annual inspections will augment the Governor's and DHS' anti-fraud efforts currently targeting the sale of various Durable Medical Equipment supplies. FDB investigators review training records at each business to verify that employees dispensing prescription medical devices and prescription medical oxygen (exemptees) have the required training and experience as indicated on exemptee license applications. FDB inspections verify whether life-supporting medical devices are properly stored and dispensed. FDB inspections also verify that HMDR exemptees are present whenever the business dispenses prescription medical oxygen and/or dangerous (prescription) medical devices. The inspections ensure that competent staff at the facility clean, sanitize, and calibrate dangerous medical devices, properly set them up in patients' homes, and maintain their function as claimed and designed.

III. ACTIVITIES, LICENSE FEES, AND COST ANALYSIS

A. License and Inspection Activities

H&S Code Sections 111625 and 111630 authorize DHS to establish fees for drug and medical device manufacturing licenses. The California Code of Regulations (CCR), Title 17, Section 10376, originally set the annual fee at $200 in 1970. After annual inflationary adjustments required by H&S Code Section 100425, the annual 2002 licensing fee for the Drug and Medical Device License is currently $402.31. Commencing January 1, 2003, DHS is to annually adjust drug and medical device fees based upon projected program costs without having to promulgate a new regulation (H&S Code Section 111656.1). Additionally, the DDS Fund was established in 2001 for the deposit of fees solely to fund drug and medical device licensing program costs.

Existing license fees now fund only about 20 percent of the cost to inspect all California drug and medical device manufacturers and to process and issue licenses. New license applicants are currently inspected as soon as they are ready to begin operating and when state investigators are available to perform the inspection. Licensed drug and medical device manufacturers are required to be inspected biennially thereafter. There is a need to increase investigator resources to maintain an adequate (and mandated) frequency of inspections. DHS has experienced some delays in completing new license inspections and biennial renewal inspections due to the many factors identified below.

- After the GMPs were adopted in 1978, DHS experienced a substantial increase in inspection time compared with the original times envisioned by the 1970 licensing and inspection program.
- The number of drug and medical device manufacturers has steadily increased at a rate of approximate five percent annually since 1985.

- Drug and medical device manufacturing has become more complex both in the nature of the finished product and in the means of manufacture. This increase in complexity has increased the potential for manufacturing hazards, thereby increasing the need for additional inspection time and oversight.
- DHS has previously relied upon FDA to provide supplemental inspection of drug and medical device manufacturers through its biennial inspection program. However, FDA is implementing many new mandates that have drained FDA inspection resources, and therefore, has not been able to provide DHS with supplemental inspection assistance.
- Drug and medical device investigators are performing other essential duties related to manufacturer licensing to assure drug and medical device safety. These include follow-up of reported injuries and deaths associated with drugs and medical devices; investigation of drugs and medical devices marketed fraudulently without appropriate licensing and marketing approvals that may be unsafe, ineffective or both; and industry and consumer education.
- The need to provide industry education has become important to assure that manufacturers, particularly new companies, understand and comply with regulatory requirements. This has utilized additional inspection resources.
- Additional training resources have been used to enhance scientific and technical knowledge due to technological advancements in the drug and medical device industry. The use of computers, gene therapy, the complexity of laboratory testing and increasing complexity of biotechnology continues to grow.

HMDR facility licensing and inspection is a new activity for DHS. Inspections are not as complex as the inspections for drug and medical device manufacturers, and are reasonably uniform. Knowledge of drug and medical device requirements is essential since HMDR facilities rent or sell both drugs (oxygen) and medical devices. Investigators must be able to determine if HMDR facilities can maintain, repair, calibrate, clean and sanitize medical equipment that is rented and reused. Most HMDR facilities sell prescription products such as respiratory support devices and medical oxygen. To sell prescription products, the facilities have to have a knowledgeable and trained person on site whenever they are open. This person is called an "exemptee," which is a term derived from the Pharmacy Board's "pharmacist exemptee." The evaluation of the "exemptee's" education, training and experience is both a function of reviewing an exemptee license application and actual testing in the field. Assisting industry in training HMDR facilities and exemptees on how to comply with all of the HMDR requirements is also an important function of this program.

B. Fee Categories and Inspection Workload

To adequately support all licensing and inspection activities for the drug and medical device programs, as well as other activities specifically required for HMDR facilities, the DDS Fund will support three separate inspection units (one unit to inspect drug manufacturers, one to inspect medical device manufacturers, and one to inspect HMDR facilities). The activities and inspections of the Drug Safety Unit and Medical Device Safety Unit are parallel, while those of the HMDR Unit are unique, combining not only consumer safety objectives but also the prevention of fraud through false medical

device and medical oxygen billing. Each unit primarily operates independently, since license requirements and applicable regulations are different and require specific knowledge and training.

Investigators must complete inspections for all new applications for Drug and Medical Device Manufacturing Licenses in a timely manner to allow the new businesses to begin operating. The licensees must then reapply annually for renewal. Inspection frequency for drug and medical device manufacturers is mandated at least once every two years. FDB can use a FDA inspection in place of a renewal inspection. In the past, FDA has inspected about 60 California licensees per year, however, it is estimated that FDA will increase that number to complete about 50 percent of the California renewal inspections in FY 2003-04. In FY 2003-04, FDB must complete approximately 485 drug and medical device manufacturing inspections. Each investigator can perform approximately 40 inspections each year. Thus, 12 Food and Drug Investigators and one Supervising Food and Drug Investigator are needed to complete all required inspections annually. Processing license applications, entering manufacturer data, and issuing licenses will require one Office Technician (OT). (See table 2).

The number of investigators and the cost of the Drug and Medical Device Licensing Program are based on the estimated minimal time to complete all licensing inspections. As now required by law, the fees charged these firms must fully fund the cost of the licensing program. The manufacturers inspected are not uniform; a new license inspection takes more time to complete than a renewal inspection, and certain manufacturers have reduced requirements. As a result of comparing the average times required to complete different types of inspections, manufacturers can be divided into three license fee categories: (1) New Applicants (New License); (2) Renewal Applicants (Renewal); and (3) New and Renewal Applicants that are small or simple operations (Special or Small Firm).

Though assignments may cross unit responsibilities, the nature of the inspections and the time to complete them is directly related to the commodity licensed. Time includes preparation, travel, inspection, exhibit evaluation, and report writing. More complex product commodities require longer inspection times. Drug manufacturers must comply with different regulations than medical device manufacturers. Prescription drug manufacturers require specific inspection elements to comply with PDMA.[1] This requirement adds approximately two hours to the inspection.

New license inspections of complex drug or medical device manufacturers take the most time and require an extensive examination of the facility, quality control, key employee qualifications, validation of processes, packaging, labeling and documentation. On average, these inspections take 58 hours for medical devices and 60 hours for drugs due to PDMA.

[1] Firms that manufacture prescription drugs are required to comply with PDMA requirements. These firms will require additional time to inspect to ensure they are in compliance with PDMA requirements. An additional PDMA fee is required from all manufacturers of human prescription drugs. This fee is established in CCR, Title 17, Section 10376 (b).

The second type of inspection is a drug or medical device manufacturer license renewal inspection. Inspection time is less than a new license inspection since some elements of the inspection can be limited to updating FDB's information files. Less explanation of requirements and inspection activities is needed as the facility is already familiar with them. There are also some new elements, such as: examining corrective actions from the previous inspection; following up on product problems, i.e., recalls and complaints; and evaluating changes and new products. On average, renewal inspections take 38 hours for medical devices and 40 hours for drugs due to PDMA. Using these average times, 20,010 hours of inspection time is necessary to provide the minimum level of consumer protection and meet mandated inspection frequencies (see Table 1). To complete these required inspections, the Drug and Device Safety Unit requires 12 investigators and one Supervising Food and Drug Investigator, as well as one Office Technician to process applications and issue licenses (see Table 2). The workload for a Senior Food and Drug Investigator performing drug or medical device manufacturing license inspections is shown in Workload Assessment Table 1.

The third type of inspection is inspections of small businesses or ones that have less quality and record keeping requirements. These include firms that repack medical oxygen, and make simple medical devices that are exempt from GMP regulations, and optical lens laboratories. New and renewal inspections for this type of manufacturer generally take the same time to complete, an average of ten hours.

The time to complete an inspection of an HMDR facility is generally uniform, and firms are similar in nature and operations. On average, a new or renewal inspection takes four hours. This includes preparation, travel, inspection, and report writing. There is often an additional hour needed to evaluate exemptee qualifications as part of the HMDR Exemptee licensing process. Fully trained Senior Food and Drug Investigators can inspect on average 300 HMDR facilities per year and complete a number of compliance reinspections, which are necessary to complete the licensing process. (see Workload Assessment Table 2). Additional time is necessary to investigate fraudulent activities, develop legal and administration actions, liaison with Medi-Cal and DHS' Audits and Investigations Branch, and provide training to HMDR exemptees and new HMDR facility owners. Two Senior Food and Drug Investigators will team with Audits and Investigations Branch Investigators and Medi-Cal to take legal actions to revoke licenses and recover Medi-Cal fraud losses. FDB estimates this will require one additional investigator in Northern and one in Southern California (see Workload Assessment Table 3). Two additional investigators are needed to verify application information, do background checks, and provide training to industry for HMDR Exemptee applicants and exemption holders (see Workload Assessment Table 4). Two Supervising Food and Drug Investigators, eight Senior Food and Drug Investigators, one Office Technician, and one Associate Governmental Program Analyst are necessary to perform all required licensing activities including: processing applications, completing HMDR Exemptee licensing, and performing required annual inspections and enforcement (see Table 3).

Using the HMDR license database, FDB estimates 480 new and 1,600 renewal HMDR license facility inspections in FY 2003-04. New and renewal license activities are generally uniform so there is no need to assess a higher fee for new applicants. New HMDR Exemptee applicants are assessed a one-time fee of $100 for evaluating

qualifications and a background check. The annual fee for the HMDR Exemptee License is $150. The current fees set by statute are adequate to provide the minimum staffing required to perform all HMDR inspection and licensing activities (see Table 5) and will remain the same.

C. Current Estimated Revenue and Estimated New License Fees

Based on current inventories and estimating new and renewal inspections, the DDS Fund will receive $1.9 million dollars in FY 2003-04. To meet the estimated mandated costs in FY 2003-04, an additional $1.3 million is needed to fund Drug and Medical Device Licensing. DHS recommends a fee increase totaling half this amount in FY 2003-04. If costs remain the same, another fee increase totaling $500,000 would be required in FY 2004-05. The licensing fee assessment is based upon average inspection time as determined for the following three categories.

License Fee Category 1: New Drug and Device Manufacturing License Applicants except those described in Category 3. Firms that have not previously been licensed by DHS require a comprehensive review of manufacturing facilities, procedures, personnel, and product labeling and advertising before licensing. DHS also offers pre-licensing guidance to new license applicants to help them understand and comply with regulatory requirements. This is a more efficient use of DHS resources than repeated regulatory inspections of firms attempting to meet licensing requirements. These license applicants require significantly more time to inspect than licensed firms that already comply with good manufacturing practices (GMP) requirements. There are extensive records, designs, validations, and procedures that must be reviewed to ensure compliance with regulations. The education, training, and experience of key personnel are reviewed and evaluated. DHS recommends that in FY 2003-04, this license fee increase from $402.31 to $1,000, and in FY 2004-05 to $1,600. Prescription drug manufacturers would pay an additional $100 as required for the PDMA evaluation.

License Fee Category 2: Licensed drug and medical device manufacturers that must comply with HSC and GMP requirements require auditing for compliance with GMP requirements. Processing, records, testing, quality assurance, and personnel are reviewed and evaluated. These inspections are generally more focused in nature and take less time than Category 1 inspections. DHS recommends that in FY 2003-04, this license fee increase from $402.31 to $850 and in FY 2004-05 to $1,300. Prescription drug manufacturers would pay an additional $100 as required for the PDMA evaluation.

License Fee Category 3: New and renewal drug and device manufacturing licensees. This category is limited to drug manufacturers that only repack medical gas or drug manufacturers with three or fewer employees, that have annual sales of less than $500,000. Medical device manufacturers in this category are limited to firms that produce medical devices that are classified by the federal regulation as "Class One" and have been exempted from GMP requirements, and firms that only manufacture optical lens (spectacle lenses). These firms require less time to inspect and have fewer records to audit. DHS

recommends that in FY 2003-04, this license fee increase from $402.31 to $625, and in FY 2004-05 to $850. Prescription drug manufacturers would pay an additional $100 as required for the PDMA evaluation.

1. HMDR Licenses:

Assuming that all facilities inspected submit the required license fee, revenues should be collected from a total of 2,080 facilities. Experience indicates that some of the "renewal" licenses will be "new" licenses that have either moved or changed location. There will also be inspections conducted on firms that are suspected to be HMDR facilities, but upon examination are exempt. The number of inspections may be higher than the number of licensed HMDR facilities. Current law limits the fee for inspecting and licensing an HMDR warehouse to one-half that of the HMDR facility. The time to complete the inspection is the same. Fortunately, the number of these facilities is low. Fees for HMDR new Exemptee applicants and Exemptee Licenses are adequate as set by the Legislature (see Table 5).

2. Estimated License Fee Revenue and Summation:

In summary, the licensing fees collected and deposited into the DDS Fund will not be adequate for the estimated costs of the licensing and inspection program until July 2004. The proposed stepped increase would generate $3,161,900 in FY 2003-04 and $3,774,875 in FY 2004-05. The Home Medical Device Retailer Facilities Act of 2000 (The Act) requires that inspection costs be borne by the regulated industry, not the General Fund. These costs are based upon the actual time needed to do the inspections and associated licensing costs. Considering the amount of time needed to complete these inspections, the increases in fees are justifiable and minimal.

HMDR license fees fully support HMDR licensing and inspection activities, and also pay for fraud investigation, exemptee evaluation, and training, which are addressed in H&S Code Division 104, Part 5, Chapter 5, Article 6 Article for HMDR facilities. The HMDR industry is supportive of this new program.

Beginning in January 2003, the funding of six current General Fund positions will shift to the DDS Fund. These positions are five Senior Food and Drug Investigators and one Office Technician. DHS recommends license fees increases effective July 1, 2003. All fees will be reassessed in the fall of 2003 and DHS will report to the Legislature again on January 10, 2004, updating the costs of these important activities and services and setting license fees as required by law.

IV: ATTACHMENTS

Table 1: Annual Mandated Drug and Medical Device Inspections

License Category	In DHS Inventory	Mandated Inspections	Done by FDA	FY2003-04 Inspections to be done by FDB	Hours to complete	Investi-gators
New License (Drug)	52	52	0	52	3120	2
New License (Medical Device)	115	115	0	115	6670	4
Renewal (Drug)	300	150	75	75	2880	2
Renewal (Medical Device)	704	352	175	175	6650	4
Special or small firms (Drug)	130	65	32	32	330	<.25
Special or small firms (Medical Device)	141	71	35	36	360	<.25
TOTALS	1442	805	317	485	20,010	12

Table 2: Estimated Drug and Medical Device Manufacturing Inspection Costs

Position	Function	Position Cost ($)	FTEs Needed	Estimated Cost ($)
Office Technician	License issuance, application contact, clerical support, staff attendance	64,938	1	64,938
Senior Food and Drug Investigator	Inspect drug and medical device manufacturers	119,441	12	1,433,292
Supervising Food and Drug Investigator	Supervise staff, provide training and liaison with industry	128,301	1	128,301
Subtotal				1,626,531
Computers	Computers for new staff, upgrades, IT support			64,400
Transportation	Vehicle replacements			64,000
Training	Required training, staff development			55,900
Estimated Program Costs				1,810,831

Costs were calculated from salaries taken from the DHS Salary Listing and are specified at the top range for each category. Benefits and overhead are taken from the Summary of DHS Standard Costs for FY 2003-04 and are specific for safety and general employees.

- Benefits/Other: includes staff benefits, retirement, and all operating expense and equipment except travel.
- Travel: includes heavy travel for investigators, and light travel for clerical and administrative positions.

Table 3: HMDR Estimated Inspection and Program Costs

Position	Function	Position Cost ($)	FTEs Needed	Estimated Cost ($)
Office Technician	License issuance, application contact, clerical support, staff attendance	64,938	1	64,938
Associate Governmental Program Analyst	Database maintenance, Exemptee program, agency liaison, legislation analysis	93,241	1	93,241
Senior Food and Drug Investigator	8 FTEs to do license inspections of HMDR facilities and 2 FTEs to investigate complaints and fraud	119,441	10	1,194,410
Supervising Food and Drug Investigator	Provide supervision and training, evaluate inspections and licenses reports, coordinate inspections and enforcement	128,301	2	256,602
Subtotal				1,609,191
Computers	Computers for new staff, upgrades, IT support			54,650
Transportation	Vehicle replacements			81,000
Training	Required training, staff development			49,000
Estimated Program Costs				1,793,841

Costs were calculated from salaries taken from the DHS Salary Listing and are specified at the top range for each category. Benefits and overhead are taken from the Summary of DHS Standard Costs for FY 2003-04 and are specific for safety and general employees.

- Benefits/Other: includes staff benefits, retirement, and all operating expense and equipment except travel.
- Travel: includes heavy travel for investigators, medium for supervisor, and light for scientific, clerical, and administrative positions.

Table 4: Drug and Medical Device Manufacturers' Estimated License Fees

Category of Drug and Medical Manufacturers	FY 03-04 # of Licenses	License Fee Revenue at $402.31	Proposed Fees for FY 03-04 ($)	Estimated FY 03-04 Revenue ($)	Proposed Fees for FY 04-05 ($)	Estimated FY 04-05 Revenue ($)
New License Fees	167	67,186	1,000.00	167,000	1,600.00	267,200
Renewal	1004	403,919	850.00	853,400	1,300.00	1,305,200
Special or Small firms	271	109,026	625.00	169,375	850.00	230,350
Totals		580,131		1,189,775		1,802,750
With PDMA		605,131		1,224,775		1,837,750

Table 5: Estimated HMDR Program Income and Estimated License Fees

HMDR Income Source	2002 Fee	Estimated No. of Licenses for FY 03-04	Proposed License Fees for FY 03-04	Estimated HMDR Income for FY 03-04
Exemptee Applicant Fee (One-time, new)	100.00	125	100.00	$ 12,500.00
Exemptee License Fee	150.00	1200	150.00	$ 180,000.00
FY 03-04 Subtotal				$ 192,500.00
HMDR Warehouses	425.00	25	425.00	$ 10,625.00
HMDR	850.00	2040	850.00	$1,734,000.00
Estimated Program Income FY 03-04*				$1,937,125.00
Estimated Program Cost FY 03-04				$1,793,841.00

*Due to the time it takes to hire and train investigators, it is unlikely that all fees will be collected in FY 2003-04.

Workload Assessment Table 1
One Senior Food and Drug Investigator Doing Drug or Medical Device Manufacturing License Inspections

Hours	Work Activity	Hours	Detailed Work Activity Components
1600	Completing 40 Manufacturing License Inspections	1260	Complete license inspection of firm's overall compliance, facility, products, procedures, labels, ingredients or components, check quality control, review employee training and experience, issue notices of violation, draft compliance actions when necessary.
		40	Preparation of inspection, e.g., review firm file, review products made and applicable requirements, review compliance status
		100	Complete travel to and from manufacturing facility
		200	Complete written report of inspection and recommend further action or licensing
200	Professional Development	80	Training courses and personal development
		80	Peace Officer training
		40	Staff and Team meetings
1800	TOTALS	1800	

Workload Assessment Table 2
One Senior Food and Drug Investigator Doing Home Medical Device Retail Facility License Inspections

Hours	Work Activity	Hours	Detailed Work Activity Components
1300	Complete 300 HMDR Facility Inspections	700	Complete HMDR facility inspections including reviewing records, inspecting medical device procedures, interviewing personnel and monitoring device and medical oxygen compliance.
		150	Complete competency and training evaluations of HMDR exemptees at facilities that handle prescription devices and medical oxygen.
		300	Complete travel to and from HMDR Facility
		150	Complete written violation notices and written inspection report
300	Complete 50 HMDR compliance reinspections of non-complying HMDR facilities	200	Complete 50 reinspections of facilities that required facility and other corrections before licensing or other regulatory action is taken.
		50	Complete travel to and from HMDR Facility
		50	Prepare HMDR reinspection reports and draft regulatory notices.
200	Professional Development	80	Training courses and personal development
		80	Peace Officer training
		40	Staff and Unit meetings
1800	TOTALS	1800	

Workload Assessment Table 3
One Senior Food and Drug Investigator Doing Fraud Investigations Of Home Medical Device Retail Facility License Inspections

Hours	Work Activity	Hours	Detailed Work Activity Components
1600	Complete 120 HMDR Facility Fraud Investigations	900	HMDR facility investigations, liaison with other agencies, collecting evidence and records, identifying ownership and legal responsibilities
		400	Writing investigation notices, requests for complaint, affidavits for search warrants
		120	Complete travel to and from HMDR Facility
		180	Testifying in court, giving depositions, meeting with prosecutors and other agencies
200	Professional Development	80	Training courses and personal development
		80	Peace Officer training
		40	Staff and Unit meetings
1800	TOTALS	1800	

Workload Assessment Table 4
One Senior Food and Drug Investigator Doing HMDR Exemptee Evaluation and HMDR Training

Hours	Work Activity	Hours	Detailed Work Activity Components
1000	Complete 65 New HMDR Exemptee Evaluations	700	Completing qualification assessment and background check of applicants
		180	Writing letters, reports and referrals related to exemptee applicants
		120	Complete travel to test and interview applicants
600	Providing Training to HMDR facility operators and HMDR Exemptee Applicants	200	Providing training seminars to HMDR facilities and HMDR Investigators
		180	Providing training for participants to meet qualifications of an HMDR Exemptee
		140	Developing and updating training presentations
		80	Complete travel to and from training sites
200	Professional Development	80	Training courses and personal development
		80	Peace Officer training
		40	Staff and Unit meetings
1800	TOTALS	1800	